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10/608,820	06/27/2003	Boris Zavizion	V0191.70030US00	7999

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EXAMINER	
FIELD, TAMMY K	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,820	ZAVIZION ET AL.	
	Examiner	Art Unit	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *20-30 and 32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 31* is/are rejected.

7)☒ Claim(s) *2,6,10* is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, and 31 are drawn to a method for selectively inactivating a parasite in a biological composition classified in class 435, subclass 7.22.

II. Claims 20-30 are drawn to a method for transfusing a subject with a blood transfusion product, classified in class 424, subclass 272.1.

III. Claims 32-34 are drawn to a transfusion product and kit classified in class 548, subclass 954.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions III and (I and II) are related as products and processes of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transfusion product can be alternatively used in materially different methods such as a disinfestant for industrial surfaces.

3. Inventions III, VII and VIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the binding molecule can be alternatively used in materially different methods such as purification of the protein and/or selection inhibition binding assays with other molecules.

4. Inventions I and II are separate and distinct methods each from the other as they comprise different preambles (biological composition versus subject), and different active method steps (inactivating blood product versus transfusing a subject with an inactivated blood product).

5. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. Additionally, in the absence of restriction would place an undue burden on the examiner, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Attn. John van Amsterdam on April 28, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-19 and 31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-30 and 32-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (27 CFR 1.143).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Priority

10. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the CIP application, 08/521,245, now U.S. Patent 6,114,108 upon which priority of 8/29/1995 is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 9-11 and 14-15 of this application. For purposes of prior art examination, the priority date of 8/29/1995 will be used for claims 1-8, 12-13, 16-19, and 31, and the priority date of 5/13/1997 will be used for claims 9-11 and 14-15.

It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/406,878, filed April 4, 2003. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

11. The disclosure is objected to because of the following informalities:

a. The use of the trademark INACTINE[tm] beginning at page 22, line 27 and DiffQuick at page 23, line 27 have been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Information Disclosure Statement

12. There appears to be no record of an information disclosure statement(s).

Claim Objections

13. The disclosure is objected to because of the following informalities:

(a) Claim 2 contains an improper Mark..sh group. Correction of claim language for example, "selected from the group consisting of" is required.

(b) Claim 6 fails to further limit independent claim 2.

(c) Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. It appears Claim 10 should depend upon Claim 9. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-6, 8-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending U.S. Application No. 10/406, 875 now U.S. PreGrant Publication 2003/0202986. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by inactivating DNA replication through modifying nucleic acids molecules using aziridino compounds in infectious entities containing a transforming DNA fragment that are found within the same biological compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-6, 8-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,093,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by selectively inactivating DNA replication through

modifying nucleic acids molecules using aziridino compounds in infectious entities containing a transforming DNA fragment that are found within the same biological compositions.

16. Claims 1-6, 8-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,352,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by selectively inactivating DNA replication through modifying nucleic acids molecules using aziridino compounds in infectious entities containing a transforming DNA fragment that are found within the same biological compositions.

17. Claims 1-4, 14, 17, 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 of U.S. Application 09/877,838 now U.S. PreGrant Publication 2002/0034724. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods appear to function the same by inactivating bacteria using aziridino compounds that are found within the same biological compositions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 1-19 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject

matter. The claims are indefinite in the recitation of "selectively inactivating" (Claim 1),"n/-W", "inclusive" (Claim 9), "inclusive" and "counter anion"(Claim 11), and "contacting the biological composition with parasiticide" (Claim 31) because it is unclear from the specification what applicant intends. Clarification is required in order to overcome this rejection.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-7, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Cook, D., *et al.* (US Patent 6,410,219 published Jan. 25, 2002 with an earlier filing date of Nov. 14, 1994).

The claims are drawn to a method for selectively inactivating a parasite in a biological composition comprising contacting the biological composition with a solution comprising an aziridino compound wherein the biological composition is blood, more specifically blood cells, platelets, and plasma derived from humans.

Cook, D., *et al.* teach a method of inactivating pathogens in human blood products (*i.e.*, whole blood, platelets, plasma, and serum) comprising adding a compound having a mustard group (inherently a parasiticide and also believed to form reactive intermediates such as aziridinium or aziridino complexes at column 8, lines 31-35) and a nucleic acid binding ligand comprising a acridine group (inherently an aziridino compound) to a blood product comprising red blood cells suspected of containing pathogens at column 4, lines 12-16. It is noted, that Applicants define "parasite" to include protozoa causing blood-born diseases such as *Plasmodium*, therefore, the Examiner views the term parasites to include pathogens such as microorganisms causing disease, thereby encompassing the broadest interpretation of protozoan parasites.

20. Claims 1-3, 7, 17-19 rejected under 35 U.S.C. 102(b) as being anticipated by Vial, H.J. *et al.* 1984. (Biochemical. Pharacol. 39(17): 2761-2770).

The claims are drawn to a method for selectively inactivating a parasite in a biological composition comprising contacting the biological composition with a solution comprising an aziridino compound wherein the biological composition is blood, more specifically blood cells, from humans.

Vial, H.J. *et al.* teach erythrocytes parasitized by *P. falciparum* cultivation in AB^+ human erythrocytes in complete medium suspensions containing AB^+ serum drug effects, *e.g.*, aziridino ethanol (inherently an aziridino compound) on parasitic growth assays at Materials and Methods, page 2762 (also see Table 1). Vial, H.J. *et al.* further teach the pattern for inhibition of *Plasmodium* growth with ethanolamine (see paragraph 2, page 2764) of IC_{50} is 12μM and aziridino ethanol of IC_{50} is 50μM (see Table 1) are the most effective inhibitors of *Plasmodium* growth.

21. Since the office does not have the facilities for examining and comparing applicants' detection and diagnosis methods with the methods disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method and the methods of the prior art (*i.e.* that the methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald *et al.*, 205 USPQ 594.

22. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vial, H.J. *et al.* 1984. (Biochemical. Pharacol. 39(17): 2761-2770), in view of Christianson, G.G. *et al.* (J. Clin. Microbiol. Apr. 1980. 11(4): 377-379).

The claims are drawn to a method for selectively inactivating a parasite in a biological composition comprising contacting the biological composition with a solution comprising an aziridino compound wherein the biological compositions. Subsequent claims are drawn to the aziridino compound contains a linear alkyl group, wherein R groups are H's, and 90%, more specifically 98% of the parasitic pathogens are inactivated.

Vial, H.J. *et al.* teach erythrocytes parasitized by *P. falciparum* cultivation in AB^+ human erythrocytes in complete medium suspensions containing AB^+ serum drug effects, *e.g.*, aziridino ethanol (inherently an aziridino compound) on parasitic growth assays at Materials and Methods, page 2762 (also see Table 1). Vial, H.J. *et al.* further teach the pattern for inhibition of *Plasmodium* growth with ethanolamine (see paragraph 2, page 2764) of IC_{50} is 12μM and aziridino ethanol of IC_{50} is 50μM (see Table 1) are the most effective inhibitors of *Plasmodium* growth.

Vial, H.J. *et al.* do not teach inactivation of parasites comprising a binary ethyleneimine dimer in biological compositions comprising serum.

Christianson, G.G. *et al.* teach a method of inactivating mycoplasms in bovine serum using cyclized binary ethyleneimine (BEI) (e.g. ethyleneimine dimmer wherein R groups are Hydrogen(s)) from 2-bromoethyleneimine (inherently contain a linear alkyl group) using varying concentrations of BEI up to 0.1 M/10 ml serum and dilution plate growth analysis at pages 377-378 (see Materials and Methods and Fig. 1). Christianson, G.G. *et al.* further teach no growth

was experienced at 0.01 M with *M. arginini* and other Mycoplasma species after 2 days postinactivation (p.i.) (see Table 1).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention to combine/substitute the aziridino compounds of Christianson, G.G. *et al.* in the method of Vial, H.J. *et al.* with the expectation of increasing the inactivation of parasites, *e.g. Plasmodium* in biological compositions using aziridino compounds because Vial, H.J. *et al.* teach that this first attempt to define relationships between the certain structural features of the drugs tested *i.e.* aziridino compounds and their inhibitory effect of the growth of *P. falciparum in vitro* should be extremely useful for the design of future structural analogs, *e.g.* Formula's II and III (see Discussion page 2769, paragraph 1).

As to Claims 9 and 11, the aziridino compounds appear to be the same and/or obvious variants over the prior art aziridino compounds. Also, the limitations wherein the method comprises an ethyleneimine oligomer present at concentrations of at least 0.005%, and ethyleneimine trimer (Claims 13, 15-16) are viewed as limitations of optimizing experimental parameters. Further, the criticality of using an ethyleneimine oligomer in at least about 0.005% (vol./vol.), and trimer *versus* binary ethyleneimine in concentrations of 0.01 Molar has not been determined, nor has using platelets, plasma, or whole blood (Claims 4-6) *versus* red blood cells or serum. Thus, the references combined render obvious the claimed invention.

Status of the Claims

23. No claim allowed.

Conclusion

24. The prior art of record and not relied upon is considered pertinent to applicant's disclosure:

a. Dayalu, K.I. *et al.* (EP 0597852 B1 published May 24, 1991) teach inactivating parasites using the know inactivating agent of binary ethyleneimine.

b. Cook, D. *et al.* (US Patent 6,410,219 B1 published Jun. 25, 2002) teach methods of inactivating pathogens in a blood product using combinations of parasiticides.

c. Windsor, G.H. *et al.* (WO 92/18161 published Oct. 29, 1992) teach methods of cyclisizing ethyleneimine.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tammy K. Field
May 29, 2004

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